AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1. (Original) An implantable medical device configured to release at least one therapeutic agent therefrom, the device comprising:

an implantable body; and

a matrix affixed to the implantable body, the matrix containing the at least one therapeutic agent therein, wherein the matrix is formed such that the concentration of the therapeutic agent in the matrix varies as a gradient relative to a surface of the matrix with a high concentration of the therapeutic agent spaced a distance from the matrix surface and a low concentration of the therapeutic agent at the matrix surface.

2. (Original) The device of Claim 1, wherein the matrix comprises a bioresorbable polymer.

3. (Original) The device of Claim 1, wherein the implantable body is substantially cylindrical.

4. (Original) The device of Claim 3, wherein the matrix is disposed in an opening in a mural surface of the implantable body.

5. (Original) The device of Claim 3, wherein the matrix is disposed in an opening in a luminal surface of the implantable body.

6. (Original) The device of Claim 3, wherein the concentration gradient of the therapeutic agent in the matrix increases from a minimum concentration of therapeutic agent at a luminal surface of the implantable body, reaches a maximum concentration of therapeutic agent in a center portion of the expandable body and then decreases towards a mural surface of the implantable body.

7. (Original) The device of Claim 3, wherein the concentration of the therapeutic agent in the matrix is higher at a mural surface of the implantable body than at a luminal surface of the implantable body.

8. (Original) The device of Claim 3, wherein the concentration of the therapeutic agent in the matrix is higher at a luminal surface of the implantable body than at a mural surface of the implantable body.

9. (Original) The device of Claim 1, wherein the matrix is disposed in an opening passing through the implantable body.

10. (Original) The device of Claim 1, wherein the matrix is disposed as a coating on the surface of the implantable body.

11. (Original) The device of Claim 1, wherein the therapeutic agent is dissolved in the matrix in a solid solution morphology.

12. (Original) The device of Claim 11, wherein the therapeutic agent is dispersed in the matrix in a solid emulsion morphology.

13. (Original) The device of Claim 1, wherein the therapeutic agent elutes from the matrix at a rate that is controlled by the concentration gradient of the therapeutic agent in the matrix.

14. (Original) The device of Claim 1, wherein the at least one therapeutic agent comprises a plurality of therapeutic agents.

15. (Original) The device of Claim 14, wherein the concentration of each of the therapeutic agents in the matrix vary with different continuous concentration gradients relative to the surface of the implantable body.

16. (Original) The device of Claim 1, wherein the therapeutic agent is selected from the group consisting of antithrombotic agents, antiproliferative agents, and antirestenotic agents.

17. (Original) The device of Claim 1, wherein the matrix is selected from the group consisting of poly(lactide-co-glycolide) (PLGA) and Poly vinylpyrrolidone (PVP).

18. (Original) The device of Claim 1, wherein the implantable body is substantially cylindrical, the matrix is disposed in a plurality of holes passing through the implantable body, and the matrix is separated from a luminal side of the implantable body by a barrier layer.

19. (Original) The device of Claim 18, wherein the therapeutic agent has a maximum concentration substantially adjacent to the barrier layer and a minimum concentration substantially adjacent to a mural surface of the implantable body.

20. (Original) The device of Claim 18, wherein the implantable body is substantially cylindrical and the holes are radial directed holes formed in a plurality of struts of the implantable body.

21. (Original) A method of forming an implantable medical device configured to release at least one therapeutic agent therefrom, wherein the therapeutic agent is disposed in a matrix affixed to the body of the implantable medical device, and wherein the concentration of the at least one therapeutic agent in the matrix varies as a continuous gradient relative to a surface of the body of the implantable medical device, the method comprising:

forming a first homogeneous solution comprising the at least one therapeutic agent mixed with a polymeric binder;

applying the first homogeneous solution to the body of the implantable medical device;

solidifying the first homogeneous solution, thereby forming a first portion of the matrix;

forming a second homogeneous solution comprising the polymeric binder;

applying the second homogeneous solution to the first portion of the matrix, thereby at least partially liquifying the first portion of the matrix; and

solidifying the second homogeneous solution, thereby forming a second portion of the matrix, wherein the concentration of the at least one therapeutic agent in the matrix is different in the first and second portions of the matrix.

22. (Original) The method of Claim 21, wherein the first and second homogenous solutions include a solvent and the first and second homogenous solutions are solidified by evaporation of the solvent.

23. (Original) The method of Claim 22, wherein the solvent comprises a miscible organic solvent.

24. (Original) The method of Claim 23, wherein the miscible organic solvent is selected from the group consisting of dimethyl sulfoxide, N-methyl pyrrolidone, ethyl lactate, and simple alcohols.

25. (Original) The method of Claim 22, wherein the solvent and the polymeric binder are both non-water soluble.

26. (Original) The method of Claim 25, wherein the non-water soluble solvent is selected from the group consisting of a poly(lactide-co-glycolide) polymer, N-methyl pyrrolidone, ethyl lactate, anisole, chloroform, tetrahydrofuran, xylene, and methylene chloride.

27. (Original) The method of Claim 21, further comprising:

applying successive homogeneous solutions to the matrix; and

solidifying the successive homogeneous solutions, thereby forming additional portions of the matrix, wherein the concentration of the therapeutic agent in the matrix is different in the successive portions of the matrix.

28. (Original) The method of Claim 21, wherein applying the first homogeneous solution to the body of the implantable medical device comprises:

introducing the homogeneous solution into a recess in the body of the expandable medical device.

29. (Original) The method of Claim 21, wherein applying the first homogeneous solution to the implantable medical device body comprises:

introducing the homogeneous solution into an opening passing through the implantable medical device body.

30. (Original) The method of Claim 21, wherein applying the first homogeneous solution to the body of the implantable medical device comprises:

coating a surface of the body of the expandable medical device with the first homogeneous solution.

31. (Original) The method of Claim 21, wherein the polymeric binder of the first homogeneous solution is water soluble.

32. (Original) The method of claim 21, wherein the therapeutic agent is selected from the group consisting of antithrombotic agents , antiproliferative agents, and antirestenotic agents.

34. (Original) The method of Claim 21, wherein the matrix is selected from the group consisting of poly(lactide-co-glycolide) (PLGA) and Poly vinylpyrrolidone (PVP).

35. (Original) The method of Claim 21, further comprising:

applying a solution of a barrier material prior to applying the first homogenous solution, the barrier material forming a barrier to the passage of the therapeutic agent in the first homogenous solution to one side of the body of the implantable medical device.

36. (Original) The method of Claim 21, wherein the second homogenous solution contains no therapeutic agent.

37. (Original) The method of Claim 21, wherein the second homogeneous solution comprises the at least one therapeutic agent, and wherein a concentration of the at least one therapeutic agent in the second homogeneous solution is different from a concentration of the at least one therapeutic agent in the first homogeneous solution.

38. (Original) The method of Claim 37, further comprising:

applying successive homogeneous solutions to the matrix; and

solidifying the successive homogeneous solutions, thereby forming additional portions of the matrix, wherein the concentration of the at least one therapeutic agent in the matrix is different in the successive portions of the matrix.

39. (Original) A method of forming an implantable medical device configured to release at least one therapeutic agent therefreom, wherein the therapeutic agent is disposed in a matrix affixed to a body of the implantable medical device, and wherein a concentration of the at least one therapeutic agent in the matrix varies as a continuous gradient relative to a surface of the implantable medical device body, the method comprising:

forming a homogeneous solution comprising a polymeric binder and a solvent;

evaporating the solvent in the homogeneous solution, thereby forming a matrix;

exposing the matrix to a solution comprising the therapeutic agent for a time sufficient to produce a partial diffusion of the therapeutic agent into the matrix such that the concentration of the therapeutic agent varies in the matrix; and

affixing the matrix to the implantable medical device body.

40. (Original) The method of Claim 39, wherein the matrix is affixed to the implantable medical device body by placing the matrix into the body prior to immersing the matrix in the solution comprising the therapeutic agent.

41. (Original) The method of Claim 39, wherein the matrix is affixed to the implantable medical device body by placing the matrix into a recess in the implantable medical device body.

42. (Original) The method of Claim 39, wherein the matrix is affixed to the implantable medical device body by placing the matrix into an opening passing through the implantable medical device body.

43. (Original) The method of Claim 39, wherein the matrix is affixed to the implantable medical device body by disposing the homogeneous solution comprising a polymeric binder and a solvent into an opening and then evaporating the solvent.

44. (Original) The method of Claim 39, wherein the matrix is affixed to the implantable medical device body by coating a surface of the implantable medical device with the matrix.

45. (Original) A method for treating a patient by local delivery of at least one therapeutic agent, the method comprising:

delivering an implantable medical device into the body of a patient, the implantable medical device having a matrix affixed to a body of the implantable medical device with concentration of the at least one therapeutic agent in the matrix varying as a gradient relative to a surface of the body matrix with a high concentration of the therapeutic agent spaced a distance from the matrix surface and a low concentration of the therapeutic agent at the matrix surface; and

delivering the therapeutic agent at a release rate and over an administration period determined by the gradient of therapeutic agent in the matrix.

46. (New) The method of Claim 45, wherein the concentration of therapeutic agent in the matrix includes a low concentration of the therapeutic agent at a surface of the matrix and a higher concentration of the therapeutic agent at a location spaced from the matrix surface.

47. (New) The device of Claim 1, wherein the concentration gradient of the therapeutic agent in the matrix increases from a minimum concentration of therapeutic agent at a matrix surface to a maximum concentration at a location spaced from the matrix surface.